

**REMARKS**

Claims 1-74 are pending in the application, with claims 1-33 and 35-43 being under examination. Claims 34 and 44-74 have been withdrawn from consideration as being directed to a non-elected invention. Claims 1, 16, 30, 32 and 42 have been amended above. Support for the amendments can be found throughout the application as filed. In particular, support for the amendments to claims 1, 16 and 32 can be found at, for example, page 41, lines 21-26; page 16, line 13 through page 17, line 20; page 17, line 26 through page 19, line 17; page 18, lines 3-4, and page 34, line 19 through page 35, line 28. Support for the amendments to claims 30 and 42 can be found at, for example, page 31, lines 17-19. Applicants have reviewed the rejections set forth in the Office Action mailed September 7, 2004, and respectfully traverse all grounds for the reasons that follow.

Applicants thank Examiners Smith and Marschel for extending a personal interview with Applicants' representatives on November 23, 2004. The amendments above and remarks below are believed by Applicant to address the subject matter discussed during the interview. Applicants respectfully request the Examiner's reconsideration and withdrawal of these rejections.

**Rejections Under 35 U.S.C. § 101**

Claims 1-33 and 35-43 stand rejected under 35 U.S.C. § 101 for allegedly being directed to non-statutory subject matter. The Office maintains that the claims either lack a physical transformation outside the computer or lack a practical application. Claims 1-33 and 35-43 also stand rejected for being directed to non-statutory subject matter allegedly because the methods merely manipulate numbers or abstract idea.

Applicants maintain that the claimed invention is directed to statutory subject matter. Claims 1, 16 and 32 have been amended to clearly specify that the claimed method of predicting a behavior of a biochemical system includes producing a comparison of data integration maps and that the identified correlative changes predict a behavior of the biochemical system which is indicative of a changing condition. The claimed methods identify actual changes in components of the biochemical system which, as described above, are useful to diagnose diseases or

intervene therapeutically. In light of these amendments, the rejections are moot and Applicants respectfully request withdrawal of these grounds of rejection.

**Rejections Under 35 U.S.C. § 112**

Claims 16 stands rejected under 35 U.S.C. § 112, second paragraph, as indefinite for use of the term “said value sets” in step (b) allegedly because it refers to the same value set referenced in step (a). Applicants have amended claim 16 to remove the term “said” in step (b), thereby distinguishing the value sets obtained in step (a). In light of this amendment, this ground of rejection is now moot and withdrawal of the rejection is respectfully requested.

Claims 30 and 42 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for repeating steps (b) and (c) allegedly because it is unclear what correlation is being compared in step (c) with the multiple integration maps produced by the claimed iterations. Applicants have amended these claims to recite that the claimed iteration is performed under a different perturbed condition. Accordingly, this ground of rejection is moot and its withdrawal is respectfully requested.

**Rejections Under 35 U.S.C. § 102**

Claims 1-33 and 35-42 stand rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Stoughton et al. The Office maintains that Stoughton et al. describe comparing microarray profiles allegedly constituting data integration maps. The profiles are alleged to consist of value sets of data elements of various behaviors such as gene expression levels, mRNA abundance and protein expression levels. The Office further alleges that comparing microarray profiles of cell cultures exposed or not exposed to perturbations is a form of comparing and identifying correlative changes in value sets.

When lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed. Cir. 1998) (quoting *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136 (Fed. Cir. 1992)). The Office must show that the single reference cited as anticipatory art describes all the elements of the claimed invention. Stoughton et al. fails to anticipate the the

claimed invention because Stoughton et al. does not describe two or more data integration maps as is claimed.

The claims have been amended to clarify that that the data integration maps and comparison thereof contain two or more different types of data. As amended, the invention claims producing a comparison of two or more data integration maps of a biochemical system where each data integration map includes at least two networks and two or more value sets which contain two or more different types of data elements. Correlative changes are identified in at least two value sets between the data integration maps where the identified correlative changes predict a behavior of a biochemical system. Stoughton et al. appears to merely compare values obtained from microarray profile without integration of different types of results into a value set as claimed. Therefore, Stoughton et al. fails to integrate two or more value sets containing different types of data elements.

The application teaches that a data integration map is a set of data elements describing the interactions, interrelations and interdependencies of network constituents when it describes:

[T]he term “data integration map” is intended to mean an indexed set of data elements corresponding to components that describes the interactions, interrelations, and interdependencies of the components included within the biochemical or constituent system. The description of the system interactions, interrelations and interdependencies can be arranged in a variety of formats . . . These formats as well as others known in the art are included within the meaning of the term so long as the represented data elements are indexed or cross-referenced to make known the various interactions, relationships and dependencies of the included system components.

Application at page 16, lines 13-29 (emphasis added).

The application also teaches that a value set means two or more types of data elements that characterize a component of biochemical system (page 18, lines 27-29, for example) and the claims now expressly recite that the two or more types of data elements constitute different types of data elements. Therefore, the methods of the invention compare two or more different types of data elements between two or more value sets for at least two networks that have been assimilated into an integration map which describes the interactions, relationships and dependencies of the network components.

The description in Stoughton et al is directed to measuring expression levels or abundance of mRNA or protein. Stoughton et al. provides no teaching to integrate such information into an integration map as claimed. Instead, Stoughton et al. is directed to methods for minimizing the measurement error in quantifying individual microarray measurements (see, for example, col. 1, lines 14-27, 38-41 and col. 4, lines 13-43) which do not include integrating different types of data to produce a representation of interactions, relationships and dependencies. Without such an integration or index describing these system attributes, Stoughton et al. cannot describe an integration map of two or more different types of data elements as claimed. Rather, the method of Stoughton et al. merely provides the results from an analysis which lacks the requisite associations included in the claimed integration maps. Accordingly, the Stoughton et al. fails to anticipate the invention as claimed and withdrawal of this ground of rejection is respectfully requested.

Claims 1-33 and 35-43 also stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Rine et al. The Office maintains that Rine et al. describe a method for generating and analyzing an output signal matrix to an output signal matrix database for correlating candidate stimuli and responses. The method is asserted to be used with an array of responder of a living thing for drug testing to identify compounds with a particular effect. The Office asserts that Applicant's distinction that the claimed value sets are composed of two or more different types of data is unpersuasive allegedly because the claims do not require different data types.

Claims 1, 16 and 32 have been amended to recite that each data integration map includes two or more value sets containing two or more different types of data elements. In light of these amendments, this rejection is now moot. Accordingly, Applicants respectfully request withdrawal of this ground of rejection.

### **CONCLUSION**

In light of the Remarks herein, Applicant submits that the claims are in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions, she is invited to call the undersigned attorney.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

  
David A. Gay  
Registration No. 39,200

4370 La Jolla Village Drive, Suite 700  
San Diego, CA 92122  
Phone: 858.535.9001 DAG:GSS  
Facsimile: 858.597.1585  
**Date: September 27, 2005**

**Please recognize our Customer No. 41552  
as our correspondence address.**

SDO 35730-1.066661.0036